

Enclosure

Check list, details to be included in budget discussions between Sponsor and Karolinska University Hospital.

Visit fee

The visit fees include all costs for preparatory work, labor and administration, completion and maintenance of CRF's and other Study related documentations, screening of patients, patient visits, material, and all the expenses incurred by the institution and Payee in performing the Study.

Additional compensation

National coordinating fee

Sponsor will reimburse the work for the Principal Investigators role as national coordinator.

Start-up cost

Site shall be reimbursed for startup activities and preparations. The cost estimate is based on time needed to prepare for the study and includes reading and training of protocol and other relevant documents and systems from the sponsor/CRO such as different procedure manuals (e.g. lab, x-ray etc.). The sponsor/CRO shall cover costs for participation in meetings related to the trial such as participation in start-up meetings (initiation visit), protocol reading/development, educational training prior to the start of the trial (e.g. eCRF, IVRS, GCP) and preparations.

Investigator meetings

The sponsor/CRO shall cover costs for travel, accommodation and preferably time spent during meeting and travelling for the staff attending from site. This includes investigators meetings, relevant scientific meetings, result meetings etc.

Patient recruitment

The sponsor/CRO shall cover costs in relation to recruitment of trial subjects e.g. advertising costs including development and administration as decided together.
The sponsor/CRO shall reimburse site for prescreening activities (e.g. telephone responses, database search etc.).

Patient travel expenses and other costs

Costs for patient travel expenses/journey, accommodation, meals shall be reimbursed by sponsor/CRO, as applicable and according to the Informed Consent Form (ICF). Preferably a unit cost per patient visit is decided upon, including administrative costs.

Screening failures

Sponsor/CRO shall compensate site for all screening failures, unless it is clear that such failure is due to negligence, malpractice, breach of protocol, willfully wrong act or omission on the part of site. The agreement can specify a certain cap of screening failures and when reached a discussion should be made between the site and sponsor/CRO prior to further screening.

Additional visit (unscheduled visit)

The sponsor/CRO shall reimburse site for the additional work related to any non-scheduled patient visits in the study, as agreed upon with the sponsor/CRO.

Unpredictable events and amendments

In the event of unexpected events such as new Case Report Form (CRF) system, protocol amendments, new Informed Consent etc, site shall be compensated for reasonable costs and time spent as reflected in an amendment to the agreement.

Administration of new Informed Consent (IC) and amendments

Administration with new IC or amendment should be reimbursed with a fixed sum per IC/amendment.

Serious Adverse Events (SAE)

In case Handling of SAE should be reimbursed and can be done separate per reported SAE.

Audit/Quality Check

The sponsor/CRO shall compensate the site for audits and other study specific extra quality checks. The calculation of the compensation will be based upon the actual hours spent.

Equipment and materials

In case of study specific electronic equipment site may need to have an electric security test made by hospital and sponsor/CRO shall cover the cost for this. If it is specified before the study that specific equipment is needed that is not available at site, the sponsor can place the equipment at site for the duration of the study, and shall reimburse site for any cost for maintenance and repair. Sponsor shall be responsible for the insurance of the equipment.

Close-out cost and archiving fee

Site shall be reimbursed for close-out activities and preparations. The cost estimate is based on time needed to close the study and includes preparation for archiving. The archiving costs shall be reimbursed by sponsor/CRO.

Hourly rate

Please see Karolinska University Hospital research price list

Currency

Payments shall preferably be in Swedish currency, SEK

Overhead

Karolinska University Hospital Research charges 15% for overhead compensation on all costs in a clinical study.

Pass through costs

All pass through costs are invoiced with Karolinska University. Hospitals OH-cost added. Pass-through costs may be invoiced separately and in dialogue with sponsor.

Retention of site payments shall not apply

Retention of site payments (including, but not limited to, withholding a percentage of agreed fees) shall not be accepted. All compensation shall be invoiced and paid based on work performed and costs incurred, in accordance with the healthcare cost-recovery principle. Any retention mechanism is considered inconsistent with these principles and shall not apply.